out to the Examiner that the instant invention does not utilize biodegradable particles incorporating a therapeutic, prophylactic or diagnostic agent and surfactant.

Straub et al. ('698) disclose and claim a method for making a microparticle formed of a synthetic biocompatible polymer useful as an ultrasound contrast agent. The microparticle is formed by emulsifying a solution of the synthetic biocompatible polymer. As stated above, the invention herein is directed to methods for preparing pharmaceutical dosage forms containing a solid pharmaceutically acceptable volatilizable agent and a pharmaceutically active ingredient. The instant invention is not directed to a method for making a microparticle formed of a synthetic biocompatible polymer useful as an ultrasound contrast agent.

Straub et al. ('300) teach a method for making a porous matrix of drug comprising an initial step of dissolving a drug in a solvent to form a solution. The purpose of the '300 disclosure is to enhance drug dissolution. In contrast, Applicant's invention does not require an initial step of dissolving a drug in solvent and is not focused on drug dissolution rate. Rather, the intent of the instant invention is to enhance compactibility of the entire drug product.

To constitute anticipation, all material elements of a claim must be found in one prior art source, In re Marshall, 198 USPQ 344 (Fed.Cir. 1978); In re Kalm, 154 USPQ 10 (CCPA 1967), which must be enabling to one skilled in the art. Akzo v. U.S. International Trade Commission, 1 USPQ2d 1241 (Fed.Cir.1986), i.e. enable that person to understand the nature and operation of the invention. Moreover, In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) states that under 35 USC 102(b), every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. Clearly, the statutory mandate for a finding of anticipation has not been met in the present case; withdrawal of the rejection under 35 USC 102(b) is requested.

The claims have been rejected under 35 USC 103(a) as being unpatentable over Straub et al ('300) in view of Remington. The Examiner's comments have been carefully considered, and the rejection is respectfully traversed.

Straub et al. ('300) teach a method for making a porous matrix of a drug for the sole purpose of enhancing dissolution. The disclosed method requires a drug be dissolved in a

volatile organic solvent to form a drug solution. The next step requires the addition of a volatile pore forming agent to form an emulsion, suspension or second solution. The volatile organic solvent and volatile pore forming agent are removed from the emulsion, suspension or second solution to yield a porous matrix having a tap density of less than or equal to 1.0 g/mL or a total surface area of greater than or equal to 0.2 m^2 /g.

According to Straub et al. at column 3, lines 40-60, and at column 4, lines 1-11, the rate of dissolution of drugs is enhanced by making the drug into a porous matrix form. The matrix must contain microparticles of drug, which preferably have a diameter between about 100 nm and 5μm. The drug matrix must be sufficiently porous to yield microparticles having these parameters. The TAP density is preferably less than about 1.0 g/ml, more preferably less than 0.8 g/ml. This level of porosity of the matrix, characterized by density, provides sufficient surface area to enhance wetting of the dry porous matrix and enhance drug dissolution.

In contrast, the instant invention does not require the dissolution steps taught by Straub et al. nor does it require the microparticles of drug having a diameter between about 100 nm and 5μm. Applicant's method utilizes a dry blend of entire drug substance. Unlike Straub et al. who focus on rate of dissolution, Applicant herein has devised a novel method to increase compressibility, which, in turn, increases rate of production and decreases cost. From the disclosure in Straub et al., it is clear that the *porous* matrix enhances the dissolution rate of drugs.

It is respectfully submitted that Applicant's invention could not be used to make the porous matrix as disclosed in Straub et al.. This is because Applicant's process, as defined in claim 1, claims a compression step following the step in which a porous second granulate is made (i.e. as the result of volatilizing a solid volatilizable agent from first granules). The compression step follows, with the granules being compressed into a tablet-like dosage form or compressed device. Application of such a compression step would likely destroy the porous matrix taught by Straub et al.

Remington contains no teaching that would remedy the defects in Straub et al. Remington simply discloses that various granulation and compression methodologies are known. It would not be obvious, however, to apply the teachings of Remington to Straub et